Michigan Department of Community Health

February 17, 2005
Re: *Pseudomonas fluorescens* alert

Dear Colleague,

Background On February 4, the FDA renewed a nationwide alert against the use of all lots of preloaded syringes containing either heparin or sodium chloride intravenous catheter flushes manufactured by the IV Flush, LLC and distributed by Pinnacle Medical Supply, of Rowlett, Texas, because new cases of infections that may be associated with the use of these unapproved and possibly contaminated products have been reported.
On January 31, 2005 FDA had warned consumers and institutions who have these preloaded syringes containing heparin or sodium chloride intravenous flushes to not use them and immediately return them to IV Flush, LLC or the original distributor.
Since that initial warning FDA has been informed of a cluster of *Pseudomonas fluorescens* infections in patients that may be associated with the heparin flushes. These cases are under investigation.
P. fluorescens is an infrequent cause of infection, but has been reported to cause outbreaks of pseudobacteremia, i.e., presence in a blood culture in the absence of clinical evidence of bloodstream infection. *P. fluorescens* has also been reported as the cause of procedure-related infections and infections resulting from transfusion with contaminated blood components.
The heparin and sodium chloride containing intravenous flushes were sold to distributors, and were then redistributed to other medical distributors and hospitals. Some of the intravenous flushes may have been provided to patients for home use. They can be identified by the syringe label, which reads in part: "IV Flush Dallas, TX." IV Flush, LLC, is notifying its distributors by phone and letter and has requested those distributors contact their customers. The company is arranging for return of all recalled products, which appear to have had limited distribution in southeast Michigan.
Clinicians with patients possibly infected from these products should report cases to their state or local health department and the FDA.
The full FDA notice is available at
http://www.fda.gov/bbs/topics/news/2005/NEW01154.html

Laboratory Action: MDCH is asking microbiologists to review culture reports for any ***P. fluorescens*** recovered from **blood, catheter tip or catheter site** since **October 1, 2004** and consult with the Infection Control professional in your hospital to determine if these products may have been involved. If it is a recent culture and the isolate is still available, please save the organism for possible further testing at MDCH Bureau of Laboratories. (Please keep in mind that there may be some issues with identification of this organism - some automated instruments may misidentify these as *P. aeruginosa*). Any suspect cases should be reported to or further discussed with either Eden Wells, M.D. or Teri Lee Dyke, R.N. in the MDCH Bureau of Epidemiology at 517-335-8165.

Thank you for your assistance in this investigation.

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